

UNITED STATES DISTRICT COURT  
SOUTHERN DISTRICT OF NEW YORK

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NEW YORK STATE RESTAURANT  
ASSOCIATION,

*Plaintiff,*

- against -

NEW YORK CITY BOARD OF HEALTH,  
NEW YORK CITY DEPARTMENT OF HEALTH  
AND MENTAL HYGIENE, and THOMAS R.  
FRIEDEN, In His Official Capacity as Commissioner  
of the New York City Department of Health  
and Mental Hygiene,

*Defendants.*

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No. 2008 Civ. \_\_\_\_\_

**MEMORANDUM OF LAW IN SUPPORT OF PLAINTIFF'S MOTION FOR  
DECLARATORY RELIEF AND A PRELIMINARY INJUNCTION**

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### **Preliminary Statement**

The New York State Restaurant Association (“NYSRA”) seeks an order enjoining enforcement of a recently promulgated regulation, New York City Health Code Section 81.50 (“Regulation 81.50”), which dictates how national chain restaurants that operate in New York City must communicate nutrition information to their customers. An earlier regulation on the same subject was struck down as unconstitutional. The new Regulation does not cure the defects of the earlier version.

*First*, Regulation 81.50 is preempted by federal law. By its terms, the Nutrition Labeling and Education Act of 1990 (NLEA) subjects restaurants to regulations promulgated by the Food and Drug Administration (FDA) concerning “nutrition claims.” 21 U.S.C. § 343(r)(2); *see* 21 C.F.R. 101.13(b)(1). Further, that federal statute expressly preempts state laws like Regulation 81.50, in which a state or local entity “directly or indirectly” establishes any requirement respecting nutrition claims that is “not identical” to the regulatory requirements of federal law. 21 U.S.C. § 343-1(a)(5). Because Regulation 81.50 imposes food labeling requirements different from (*i.e.* not “identical to”), the federal regulations, it is expressly preempted by the NLEA and void under the Supremacy Clause

*Second*, the Regulation violates the First Amendment rights of plaintiff’s members in two ways. To begin, the Regulation violates the prohibition of compelled speech, most recently applied by the Supreme Court in *United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001). As *United Foods* explains, even in the context of commercial speech, the government simply may not force a private party to convey the *government’s* message as if it were the private party’s message when the private party wants to convey a different message or no message at all. Here the Board of Health has transformed the restaurants’ simple commercial message on their

menu boards (“Hamburger, \$1.99”) into the *government’s* health message (“Hamburger, 500 calories”), conveying the *government’s* view of the singular importance of calories above all other nutrition or health information, such as information about fat content, carbohydrates, sodium, sugar, balanced diets, or any other information.

There simply can be no doubt that Regulation 81.50 was designed first, to force private restaurant owners to convey the government’s message about how people should lead “better lives,” and second, to force customers to look at the message if they want to eat at the restaurant in question. As Mayor Michael Bloomberg put it, “Anyone who thinks we’re going to walk away from trying to tell the public what they’re eating and what it’s doing to them doesn’t understand the obligation this city’s health department has . . . . We have to tell people how to lead better lives.” Ray Rivera, *Fight to Put Calories on Menus May Widen*, N.Y. TIMES, Sept. 13, 2007, at B3. Maybe the city’s Health Department has the right to “tell people how to lead better lives.” It does not have the right, however, to force private restaurant owners to “tell [other] people how to lead better lives,” using their *own* property to convey the *government’s* message in a manner that makes it appear to be the restaurant’s message. And it does not have the right to force people to look at that message if they decide to eat at that restaurant.

In addition, Regulation 81.50 cannot survive even the more forgiving intermediate scrutiny set forth in *Central Hudson Gas & Electric Corp. v. Public Service Comm’n of New York*, 447 U.S. 557, 566 (1980). Under the doctrine of *Central Hudson*, the burden falls on the city (a) to identify a substantial government interest, (b) show that the Regulation is effective in directly advancing that interest, and (c) show that the Regulation is not more extensive than is necessary to further the interest. The Board of Health contends that the Regulation will further the interest of public health by reducing the incidence of obesity in the general population. But

the city cannot carry its burden to demonstrate that the Regulation will be effective in achieving that goal, and it cannot explain why reasonable and less burdensome alternatives would be ineffective.

## **FACTS**

### **A. Obesity and the Communication of Nutrition Information**

No one knows how to reverse the trend of increasing obesity in the United States. Even on subjects as seemingly simple as the communication of nutrition information and how (or whether) consumers use the information, there are questions but not answers. After more than a decade of comprehensive nutrition labeling on packaged foods mandated by federal law, the incidence of obesity continues to rise. With respect to the much more complicated issue of foods sold by the variety of restaurants in the United States, one recent government-sponsored report concluded that there is no public health consensus on how consumers use nutrition information in restaurants or whether such information could help reduce the incidence of obesity:

There is a clear need for more research regarding how the provision of nutrition information, claims (such as “low calorie”), and symbols influence consumer preference and choice for away-from-home food consumption situations. Of particular concern is how, when, and why consumers use nutrition information and claims during their decision-making processes. More specifically, a better understanding is needed of the types of factors that moderate consumers’ responses to the provision of nutrition information and claims for away-from-home foods.<sup>1</sup>

The Report includes a long list of suggested research areas for addressing the unanswered questions, stating that “[t]he range of views on this topic, outlined here, may help the reader to understand the complexity of the issue and the diverse and sometimes strong views that the topic

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<sup>1</sup> The Keystone Center, *The Keystone Forum on Away-From-Home Foods: Opportunities for Preventing Weight Gain and Obesity*, Final Report, May, 2006, at 13, available at [http://www.keystone.org/spp/documents/Forum\\_Report\\_FINAL\\_5-30-06.pdf](http://www.keystone.org/spp/documents/Forum_Report_FINAL_5-30-06.pdf).

generates among stakeholders.” *Id.* at 70. The Report highlights many of the unanswered questions:

What type of information should be provided? . . . How and where should information be provided, given the goals for providing such information? At point of sale, before sale, after sale for future purchases, etc.? Via menu board, brochure, table tent, poster, kiosk, etc.? If the information is accessed, how is it used? Under what circumstances is current behavior influenced and under what circumstances is future behavior influenced? For example, if consumers consume an extra 100 calories at lunch, will they eat a lighter dinner? . . . Is information on the caloric content of food items more likely to be used by the consumer when presented alone or when embedded in general nutrition content information?

*Keystone Forum Final Report*, at 84.

Legislative and regulatory actions (described below) confirm that the federal government has determined that the effective communication by restaurants of nutrition information to customers is a complex and uncertain subject; that there is no one “right way” to communicate this information; that restaurants should be permitted and encouraged to try different ways of communicating; and that they should not be burdened by specific requirements that would hinder experimentation. Congress has given the FDA plenary authority over the nutrition content claims (*e.g.*, “contains 100 calories”) when they are made by restaurants. The FDA, in turn, has given restaurants flexibility in determining whether and how to communicate such claims. The NLEA prohibits states from imposing any different or additional requirements. (*See infra* pp. 19-20.)

#### **B. NYSRA Members’ Provision of Nutritional Information.**

Against this backdrop, some restaurants in New York City publish comprehensive nutrition information about the food items they sell. *See, e.g.*, DeMuth Decl. ¶¶ 7, 10; Haugen Decl. ¶¶ 3, 7-12; LeClair Decl. ¶ 3; Liewen Decl. ¶¶ 4-7; Roach Decl. ¶ 2; Smoot Decl. ¶ 4.

They publish this information in order to assist their customers to make healthful and appropriate food choices. They believe that overemphasis on any one nutrient such as calories can interfere with consumers obtaining a healthy, varied diet. *See, e.g.*, DeMuth Decl. ¶¶ 3, 11; Haugen Decl. ¶¶ 4, 14-18; LeClair Decl. ¶ 5. Realizing that consumers have individual dietary needs and restrictions, these restaurants believe that the best way to serve their customers is to provide them with a complete nutritional breakdown of their menu items—one that includes factors such as fat, saturated fat, dietary fiber, sugar, cholesterol, protein, carbohydrate, sodium, and vitamin and mineral content, as well as recommended percentages of daily consumption values and calories. Such restaurants provide comprehensive nutritional information on premises—through brochures, on-package labeling, posters, and tray liners—or on websites or on both. *See, e.g.*, DeMuth Decl. ¶¶ 7, 10; Haugen Decl. ¶¶ 7-12; LeClair Decl. ¶ 3; Liewen Decl. ¶¶ 4-7; Roach Decl. ¶ 2. Customers have the opportunity to compare and contrast the nutritional content of various food items which, these restaurants believe, leads to more informed choices based on each consumer's individual needs. However, only a very few restaurants post calorie information on menus or menu boards, which have limited space for advertising the food.

**C. New York City's Original Regulation 81.50.**

On December 5, 2006, the Board of Health adopted a regulation addressing calories on the menu boards of restaurants. The regulation provided that any restaurant voluntarily making nutritional information publicly available on or after March 1, 2007 would be required to post that information in a preordained on its menus and menu boards. In other words, the regulation applied only to restaurants that already disclosed calorie information. In response to comments questioning whether the Regulation would achieve its stated goal of reducing obesity, the Board of Health said it would have to evaluate the health impact of the measure after it was put into

effect.<sup>2</sup>

**D. Unconstitutionality of Original Regulation 81.50.**

Before the original Regulation 81.50 took effect, plaintiff commenced an action under 42 U.S.C. § 1983, seeking relief for violations of the First Amendment and the Supremacy Clause and moving for a preliminary injunction to enjoin enforcement of the regulation. Several *amici* appeared in the case in support of the defendants.

The court issued an opinion in favor of plaintiff, permanently enjoining the regulation on the ground it was preempted by 21 U.S.C. § 343(r) and its associated preemption provision, § 343-1(a)(5). *New York State Rest. Ass'n v. New York City Bd. of Health*, 509 F. Supp. 2d 351 (S.D.N.Y. 2007) (*NYSRA I*). The court held for NYSRA on preemption grounds and did not reach the issue of whether original Regulation 81.50 also violated the First Amendment. (It was this ruling that prompted Mayor Bloomberg's statement, quoted on page 2, above.)

The district court's opinion accompanying its injunction contained *dicta* setting out a road map for how the city could write a lawful regulation. According to the court, a new regulation (like some proposed elsewhere in the United States) that required restaurants to post calories in specified ways and did not apply only to those who already provided calorie information would not be preempted. The court's opinion stated that "mandatory" statements by restaurants (*i.e.*, those required by state law) are not "nutrition content claims" within the meaning of section 343(r) and therefore would not be preempted. Neither the city nor its *amici* made this argument to the court. As we discuss below, the reasoning of the district court in its *dicta* is not sound. Whether a statement about the calorie content of food is a "nutrient content

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<sup>2</sup> Summary and Response to Public Hearing and Comments Received Regarding Section 81.50 at 4 (Nov. 27, 2006).



claim” under federal law does not depend on whether it is made voluntarily or in response to a state law or rule requiring it.

**E. Promulgation of a New Version of Regulation 81.50.**

True to the views of the mayor, the Board of Health seized on the district court’s *dicta* as a roadmap for a menu board regulation that it hoped would survive constitutional challenge. On January 22, 2008, the Board promulgated a new version of Regulation 81.50. The Board’s stated rationale for the regulation is that posting calorie information on restaurant menus and menu boards “can reasonably be expected to reduce obesity and the many health related problems which obesity causes.” Notice of Adoption of a Resolution to Repeal and Reenact § 81.50 of the New York City Health Code (Jan. 22, 2008) p. 2 (“Notice of Adoption”).

The new version mandates all chain restaurants with fifteen or more locations nationally (not just those making nutritional information available voluntarily), to display calorie content in the manner prescribed by the regulation. The Board states that the regulation covers only 10% of New York City’s restaurants, leaving 90% unaffected. Notice of Adoption at 10. However, the Board contends that the regulation will affect roughly one-third of restaurant *meals*, leaving at least two-thirds of restaurant meals unaffected by the regulation.

For those restaurants affected, the calorie information must be listed clearly and conspicuously, adjacent or in close proximity to the menu item, and the font and format of calorie information must be as prominent in size and appearance as the name or price of the menu item. The regulation seems to apply well beyond menu boards and what is ordinarily thought of as menus. Restaurants are left to guess if it includes material posted on the windows of a restaurant, all the tents on the tables, all posters throughout the restaurant, and at least according to the literal definition of “menu” in the regulation, advertising in newspapers, and flyers. Olsen Decl.

¶ 3. The Board's Notice of Adoption does not say why this sweeping definition will further the Board's objective of putting calorie information at the so-called point of purchase.

Finally, the regulation applies equally to customized and combination offerings. In such cases, the regulation requires the restaurant to post a "range," minimum to maximum, of the possible calories.

#### **F. Response to New Regulation 81.50**

NYSRA believes that the revised Regulation 81.50 infringes on the rights of its members. Members who have already provided nutrition information to their customers have concluded that displaying calories in isolation will inaccurately overemphasize the importance of calories to a well-balanced diet and neglect the relevance of other important nutrients and other contributing causes of obesity. They believe that forcing restaurants to highlight calories in isolation from other nutrients increases the risk that consumers will ignore other nutritional information that restaurants would like to provide to them. *See, e.g.,* DeMuth Decl. ¶¶ 3, 11; Haugen Decl. ¶¶ 14-18; LeClair Decl. ¶ 5. Other NYSRA members do not want to list calories because they are concerned about the extreme difficulty of making accurate statements given the natural variation in the execution of their recipes from meal to meal. *See* Randolph Decl. ¶¶ 3-8.

For some NYSRA members subject to the Regulation, menus and menu boards are the most valued space in the restaurants. *See* Fitzgerald Decl. ¶ 3; Munoz Decl. ¶ 3; Smoot Decl. ¶ 3. Available space on menus and menu boards is already very limited. Adding calorie information will result in menus and menu boards that are cluttered and that in all likelihood will need to use very small font sizes. This will make them confusing and difficult for consumers to read, directly interfering with the ability of such restaurants to communicate with their customers. *See* Liewen Decl. ¶ 10; Munoz Decl. ¶¶ 5-6; Smoot Decl. ¶ 15.



Regulation 81.50 has established a rigid and irrational regime. Although the original regulation held out the promise that the Department of Health would accept alternatives to posting on menus and menu boards, that promise proved illusory when the Department rejected reasonable alternatives such as counter mats at the point of purchase or signs on stanchions. *See* Horn Decl. ¶¶ 2-4; Munoz Decl. ¶ 12; Smoot Decl. ¶¶ 8-10. In the new version of Regulation 81.50, no such flexibility is offered; rather, the city rigidly requires posting on the menus and menu boards (as broadly defined).

Finally, there is no evidence that the regulation will accomplish its stated goal of reducing obesity. Plaintiff has submitted a declaration by Dr. David Allison, one of the country's leading experts on obesity. He discusses the questions that would need to be answered before one could decide whether Regulation 81.50 would be effective in its stated goal. Many of these questions echo the questions that the *Keystone Forum Final Report* had suggested as topics for research. The only way to come to a conclusion on the effectiveness of a regulation like the one before the Court is to speculate about the answers to these many questions (and others as well). Dr. Allison concludes, based on an extensive literature review, that the current state of knowledge (or, more accurately, lack of knowledge) could lead to three different (and contradictory) hypotheses, each of which would be as plausible as the other. One could speculate that the regulation might be effective; or, one could speculate that it might be ineffective; or one could speculate that it might indeed be counterproductive. As for evidence—as opposed to speculation—there is none. *See infra* pp. 34-38.

### **ARGUMENT**

Under Rule 65, a plaintiff can obtain a preliminary injunction against infringement of constitutional rights by the state. *See Green Party of New York State v. New York State Bd. of*

*Elections*, 389 F.3d 411, 418 (2d Cir. 2004). A preliminary injunction is proper where a plaintiff shows (a) irreparable harm, and (b) a likelihood of success on the merits. *Id.*; *Long Island R.R. Co. v. International Ass'n of Machinists*, 874 F.2d 901, 910 (2d Cir. 1989); see *International Dairy Foods Ass'n v. Amestoy*, 92 F.3d 67, 70 (2d Cir. 1996) (“because the injunction at issue stays ‘government action taken in the public interest pursuant to a statutory . . . scheme,’ this Court has determined that the movant must satisfy the more rigorous ‘likelihood of success prong’”) (quoting *Able v. United States*, 44 F.3d 128, 131-32 (2d Cir. 1995)).

# **I. PLAINTIFF’S MEMBERS WILL SUFFER IRREPARABLE HARM ABSENT AN INJUNCTION**

When a preliminary injunction is sought to prevent infringement of First Amendment rights, irreparable harm is presumed. See *Green Party of New York State*, 389 F.3d at 418; *International Dairy Foods Ass'n*, 92 F.3d at 71 (“It is established that ‘[t]he loss of First Amendment freedoms, for even minimal periods of time, unquestionably constitutes irreparable injury.’”) (citation omitted); *Statharos v. New York Taxi & Limousine Comm'n*, 198 F.3d 317, 322 (2d Cir. 1999) (where “plaintiffs allege deprivation of a constitutional right, no separate showing of irreparable harm is necessary.”). Similarly, enforcement of a local law that is preempted by a federal statute also constitutes irreparable harm. See *Morales v. Trans World Airlines, Inc.*, 504 U.S. 374, 381 (1992) (injunctive relief warranted where local law enforcement officials threaten to apply state statute in the face of a preemptive federal law). A preemption statute constitutes a “federally created right to have only one regulator” with regard to the issue at hand. *Trans World Airlines, Inc. v. Mattox*, 897 F.2d 773, 784 (5th Cir. 1990), *aff'd in part and rev'd in part on other grounds sub nom. Morales v. Trans World Airlines, Inc.*, 504 U.S. 374 (1992). Hence, “permitting states to regulate” where Congress has preempted state regulation

“would violate the Supremacy Clause, causing irreparable injury . . . .” *Id.*; *VRC LLC v. City of Dallas*, 460 F.3d 607, 611 (5th Cir. 2006) (“In an express preemption case . . . ‘the finding with respect to likelihood of success carries with it a determination that the other three requirements, [including irreparable harm,] have been satisfied.’”) (citation omitted).

## **II. FEDERAL LABELING LAW PREEMPTS REGULATION 81.50<sup>3</sup>**

The Supremacy Clause permits Congress to preempt any state law that conflicts with the exercise of federal power. “Pre-emption fundamentally is a question of congressional intent and when Congress has made its intent known through explicit statutory language, the courts’ task is an easy one.” *English v. General Elec. Co.*, 496 U.S. 72, 78-79 (1990) (citation omitted).

Federal regulations “have no less a pre-emptive effect than federal statutes.” *Fidelity Fed. Savings & Loan Ass’n v. de la Cuesta*, 458 U.S. 141, 153 (1982).

To determine whether Regulation 81.50 is preempted, courts follow a well-established two-step analysis, answering: (i) is presentation of calories and other food nutrients governed by federal law; and (ii) if so, does federal law expressly preempt Regulation 81.50. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51, 56 (2002); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867 (2000). Because the answer to both questions is yes, Regulation 81.50 must be declared void.

### **A. Overview of The Nutritional Labeling and Education Act of 1990 and Implementing Regulations**

The NLEA regulates disclosure of the nutritional content of foods in two related areas: subsection (q) imposes mandatory labeling requirements for packaged foods, resulting in the

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<sup>3</sup> Although plaintiff need only show a likelihood of success, the statute’s preemptive effect does not turn on any facts reasonably subject to dispute. For that reason, this claim is ripe for declaratory judgment and summary judgment.

familiar nutrition labels found on packaged foods throughout the United States; and subsection (r) gives the FDA regulatory authority over nutrient and health benefits claims about food. 21 U.S.C. §§ 343(q), (r).<sup>4</sup> Acting under authority delegated in subsection (r), the FDA has promulgated regulations governing such claims. *See* 21 C.F.R. § 101.13. The FDA's implementing regulations govern "nutritional claims or other nutrition information in any context" in restaurants. *See* 21 CFR §§ 101.9(j)(2), 101.13(n). Such regulations have the force of law and are "binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute." *United States v. Mead Corp.*, 533 U.S. 218, 227 (2001) (footnote omitted).

Subsection (q) provides that restaurants are wholly exempt from its nutrition labeling requirements. 21 U.S.C. § 343(q)(5)(A)(i). In this way, the NLEA requires "Nutrition Fact Panels" for packaged food, but not for restaurant food. In contrast to subsection (q), which requires nutrition information panels on packaged food, subsection (r) governs the much broader category of nutrition claims and health claims. Also in contrast to subsection (q), subsection (r) contains only a limited exemption for restaurants.<sup>5</sup> Outside the limited and specified exemptions, the FDA's implementing regulations apply to *all* nutrient content claims made by restaurants. 21 C.F.R. § 101.9(j)(2)(i); *see* 21 U.S.C. § 343(r)(2)(A)(i); *see Public Citizen, Inc. v. Shalala*, 932 F. Supp. 13, 15 (D.D.C. 1996).

<sup>4</sup> The NLEA, Pub. L. No. 101-535, 106 Stat. 4501, added new subsections 403(q) and (r) and 403A to the Federal Food, Drug and Cosmetic Act ("FDCA"). Some of the relevant provisions of the NLEA are codified at 21 U.S.C. §§ 343(r) and 343-1(a)(5), and others are not codified, but are set out as a note following 21 U.S.C.A. § 343(r).

<sup>5</sup> Restaurants are exempt from subsection (r) only to the extent that they make claims relating to (1) cholesterol, (2) saturated fat, (3) dietary fiber, or (4) nutrients that increase the risk of disease. *Compare* 21 U.S.C. § 343(q)(5)(A)(i) *with* § 343(r)(5)(B).

The NLEA contains express preemption provisions that track subsections (q) and (r). 21 U.S.C. §§ 343-1(a)(4), (5). Each preemption provision prohibits state laws and regulations unless they impose requirements “identical to” the relevant federal standard. Each preemption provision also contains an exemption from preemption that tracks the substantive exemption for restaurants. Restaurants are completely exempt from subsection (q), and the corresponding preemption provision completely exempts state regulation of restaurant labels from its reach. 21 U.S.C. § 343-1(a)(4). Courts have thus held that subsection (a)(4) does not preempt state law concerning restaurants, because restaurants are exempt from section 343(q) and thus equally exempt from its preemption section. *See Pelman v. McDonald’s Corp.*, 237 F. Supp. 2d 512, 526 (S.D.N.Y. 2003); *but see Cohen v. McDonald’s Corp.*, 347 Ill. App. 3d 627, 808 N.E.2d 1 (Ill. Ct. App. 1st Dist. 2004) (state law claims preempted under § 343-1(a)(4)).

Just as restaurants are only *partially* exempt from subsection (r), the corresponding preemption provision only *partially* exempts from its reach state regulation of restaurant claims. 21 U.S.C. § 343-1(a)(5). Thus, the relevant statutes for restaurants—and for evaluating Regulation 81.50, which seeks to require some restaurants to post calorie information on their menus and menu boards—are 21 U.S.C. §§ 343(r) and 343-1(a)(5). Courts have held that subsection (r) *does* preempt state law concerning nutrient content claims made by restaurants, because restaurants are generally *not* exempt from subsection (r) and thus equally *not* exempt from its preemption section. *NYSRA I*, 509 F. Supp. 2d at 509; *Reyes v. McDonald’s Corp.*, Nos. 06 C 1604, 06 C 2813, 2006 WL 3253579, at \*4 (N.D. Ill. Nov. 8, 2006) (factual disclosures about the quantity of nutrients [*e.g.*, 520 calories in a large serving of french fries] were “nutrient content claims” under the NLEA).

**B. Statements of Total Calories Are Nutrient Content Claims Under Section 343(r)**

Regulation 81.50 regulates the disclosure of total calories, requiring statements of the amount of calories and regulating the manner of their presentation. Such statements are within the unambiguous coverage of subsection (r) of the NLEA and within the coverage of the FDA's implementing regulations.

In *NYRSA I*, the city and its *amici* argued that the original Regulation 81.50 was not preempted because it did not regulate “nutrient content claims” within the meaning of § 343(r) and its preemption provision, § 343-1(a)(5). According to the city, a simple statement of the amount of a nutrient (*e.g.*, “100 calories”) is not a “claim” within the statute and regulations. According to this argument, a “claim” is made only when the statement can be said to describe the nutrient in “qualitative” terms (as in “low in calories”). The city and its *amici* cited floor statements,<sup>6</sup> supposed congressional policy, and letters written by staff of the FDA,<sup>7</sup> rather than the text of the statute and the implementing regulations.

This reading of the statute and regulations was rejected by the district court in *NYRSA I*, just as it had been rejected by an earlier district court holding, *Reyes v. McDonald's Corp.* 2006 WL 3253579, at \*4. For the reasons we discuss below, those holdings are correct. They are compelled by the text of the statute and by the text of the implementing regulations. A statement of the amount of the nutrient, without more, is a “nutrient content claim” covered by the NLEA.

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<sup>6</sup> “Floor statements are among the most dangerous and least reliable forms of legislative history.” *Hayen v. Pataki*, 449 F.3d 305, 353 (2d Cir. 2006) (Parker, J., dissenting); *see also Barnhart v. Sigmon Coal Co.*, 534 U.S. 438, 457 (2002) (there is “no reason to give greater weight to the views of two Senators than to the collective votes of both Houses, which are memorialized in the unambiguous statutory text.”) (footnote omitted).

<sup>7</sup> “Interpretations such as those in opinion letters—like interpretations contained in policy statements, agency manuals, and enforcement guidelines, all of which lack the force of law—do not warrant *Chevron*-style deference.” *Christensen v. Harris County*, 529 U.S. 576, 587 (2000).



**1. The Statutory Text Compels the Conclusion that Statements of the Amount of Calories are “Claims”**

Three provisions of the NLEA demonstrate that a statement of the amount of calories is a “claim” within the meaning of the statute and implementing regulations. *First*, the statute declares food “misbranded” if it bears a “claim . . . made in the label or labeling of food which expressly or by implication . . . characterizes the level of [specified nutrients including ‘total calories’]” unless “the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary.” 21 U.S.C. §§ 343(r)(1)(A), (r)(2)(A)(i).<sup>8</sup> Subsection (r) thus covers any “claim” that “expressly or by implication characterizes the level” of “the total number of calories.”

*Second*, a provision of the statute specifically instructs the FDA to promulgate regulations that would “permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in [§ 343(r)] . . . .”<sup>9</sup> Thus, Congress specifically intended that the FDA promulgate rules regulating “statements describing the amount” of calories and other nutrients.

*Third*, section 343(r)(1) provides that nutrition fact statements required by subsection (q) on food labels (including the total calories) are not claims subject to subsection (r) *when they are presented in the nutrition fact panel*. 21 U.S.C. § 343(r)(1)(B).<sup>10</sup> Thus, if the statement 100

<sup>8</sup> Subsection (q)(1), incorporated for this special purpose by subsection (r)(1)(A), requires nutrition labels to include “the total number of calories.” 21 U.S.C. § 343(q)(1)(C).

<sup>9</sup> NLEA, Pub. L. No. 101-535, § 3(b)(1)(A)(iv), 106 Stat. 4501 (set out in Historical and Statutory Notes after 21 U.S.C.A. § 343(r)).

<sup>10</sup> This provision provides, in part:

A statement of the type required by paragraph (q) . . . that appears as part of the nutrition information required or permitted by such paragraph is not a claim which is subject to this paragraph . . . .

21 U.S.C. § 343(r)(1)(B).

calories “appears as part” of the nutrition fact panel required by subsection (q), it is not a “claim” within the meaning of subsection (r)(1). By carving out statements that “appear as part” of the federally required nutrition panel, the statute confirms that when the very same statements appear *elsewhere* on label or labeling—*i.e.*, in locations *not* required by subsection (q)—then they *do* constitute “claims.” See H.R. Rep. No. 101-538 at 19 (1990), 1990 U.S.C.C.A.N. 3336, 3349 (“Section 403(r)(1) . . . removes the statements as to the amounts of nutrients required by section 403(q) from the disclosure and other requirements of section 403(r). However, section 403(r) would apply to any statement that is not required by section 403(q), *including a statement identical to that on the nutrition label which appears on the front panel of the product.*”) (emphasis added).

**2. Regulations that Have the Force of Law Compel the Conclusion that Statements of the Amount of Calories are “Claims”**

Consistent with these statutory directives, FDA regulations—which have the force of law—confirm that a statement describing the amount of calories in numerical terms is a “claim” within the meaning of the statute and regulations. Such regulations, promulgated after a notice-and-comment process, are of “controlling weight,” (*United States v. Haggard Apparel Co.*, 526 U.S. 380, 392 (1999)), and are “binding in the courts unless procedurally defective, arbitrary or capricious in substance, or manifestly contrary to the statute.” *United States v. Mead Corp.*, 533 U.S. at 227 (footnote omitted).

First, in 21 C.F.R. § 101.13(b)(1), the FDA defines an “expressed nutrient content claim” as “any direct statement about the level (or range) of a nutrient in the food, e.g., ‘low sodium’ or ‘contains 100 calories.’” 21 CFR § 101.13(b)(1) (emphasis added). If “contains 100 calories” is



a nutrient content claim under the statute, common sense dictates that “100 calories” is also a nutrient content claim.

*Second*, having thus defined a “claim” (to include “contains 100 calories”), the regulations elsewhere govern what are permissible and what are impermissible express and implied claims. These regulations confirm that the statement “100 calories” is regulated by the FDA under authority of subsection (r). Subsection 101.13(i) provides that a label “may contain a *statement* about the *amount* or percentage of a nutrient,” so long as “[t]he statement does not in any way implicitly characterize the level of the nutrient in the food [such implicit characterizations being subject to other subparagraphs] and it is not false or misleading in any respect (e.g., ‘100 calories’ or ‘5 grams of fat’) . . . .” 21 CFR § 101.13(i)(3) (emphasis added).<sup>11</sup> In short, the FDA regulations promulgated under authority of subsection (r) *define* a

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<sup>11</sup> This subsection provides:

(i) Except as provided in 101.9 or 101.36, as applicable, or in paragraph (q)(3) of this section, the label or labeling of a product may contain a statement about the amount or percentage of a nutrient if:

(1) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is consistent with a definition for a claim, as provided in subpart D of this part, for the nutrient that the label addresses. Such a claim might be, “less than 3 g of fat per serving;”

(2) The use of the statement on the food implicitly characterizes the level of the nutrient in the food and is not consistent with such a definition, but the label carries a disclaimer adjacent to the statement that the food is not “low” in or a “good source” of the nutrient, such as “only 200 mg sodium per serving, not a low sodium food.” . . . or

(3) The statement does not in any way implicitly characterize the level of the nutrient in the food and it is not false or misleading in any respect (e.g., “100 calories” or “5 grams of fat”), in which case no disclaimer is required.

“claim” to include “contains 100 calories” and *regulate* a claim of “100 calories.”

*Third*, 21 C.F.R. § 101.13(c) confirms that a statement of the amount of a nutrient anywhere *other than* on a federally required nutrition fact panel is a “nutrient content claim”:

Information that is required or permitted by § 101.9 [mandatory nutrition labeling requirements for food] or § 101.36 [mandatory labeling requirements for dietary supplements], as applicable, to be declared in nutrition labeling, and that appears as part of the nutrition label, is not a nutrient content claim and is not subject to the requirements of this section. **If such information is declared elsewhere in the label or in labeling, it is a nutrient content claim and is subject to the requirements for nutrient content claims.**

21 CFR § 101.13(c) (emphasis added).

The FDA’s notice of final rulemaking for these regulations confirm the agency’s intent to govern simple factual information like “100 calories.” During the notice and comment period, the FDA was asked to *exclude* statements about “simple factual information” from the definition of “nutrient content claim” on the theory that such a statement is not “a claim that ‘characterizes’ the level of any nutrient” within the meaning of the statute. 58 Fed. Reg. 2302-01, at 2303 (Jan. 6, 1993). The comment argued that “a statement of the type contained in nutrition labeling—for example, that a food contains 25 calories per serving . . .—is not a claim characterizing the level of the nutrient.” *Id.* The FDA rejected that contention, embraced the view that a quantitative factual statement about the amount of a nutrient is a “claim” that “characterizes the level” of the nutrient within the meaning of the statute, and promulgated final and binding regulations to that effect:

The agency . . . does not agree that the scope of the statute and the regulations excludes statements of the amount of a nutrient in a food. The [distinction] the comment draws between “nutrient descriptors” and “nutrient content” claims is unpersuasive . . . .

[I]f statements of the amount and percentage of nutrients were not subject to section 403(r)(1)(A) of the act, there presumably would have been no need for Congress to express its desire that such claims be permitted by the regulations. Accordingly, FDA concludes that section 403(r)(1)(A) of the act and therefore these final regulations apply to statements of the amount of a nutrient in food as well as to statements of the level of a nutrient in food.

*Id.* at 2303-04.

This is the same conclusion the district court reached in *NYSRA I*.

**C. The FDA Has Chosen to Give Restaurants Flexibility in Disclosing Nutritional Information**

The FDA has promulgated a special rule for nutrient content claims by restaurants. 21 C.F.R. §101.10. The rule expressly grants restaurants flexibility to present accurate information concerning nutrient claims in any reasonable manner:

Nutrition labeling in accordance with § 101.9 [specifying nutrition facts required on labels] shall be provided upon request for any restaurant food or meal for which a nutrient content claim . . . is made, except that information on the nutrient amounts that are the basis for the claim (e.g., “low fat, this meal provides less than 10 grams of fat”) may serve as the functional equivalent of complete nutrition information as described in § 101.9. Nutrient levels may be determined by nutrient data bases, cookbooks, or analyses or by other reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim. Presentation of nutrition labeling may be in various forms, including those provided in § 101.45 [concerning certain unprocessed foods] and other reasonable means.

21 C.F.R. § 101.10. Thus, the FDA has given restaurants great flexibility to decide how to communicate nutrient information to customers and how to determine nutrient levels. For example, a restaurant may communicate nutrition information through in-store signs, posters, brochures, notebooks or charts, as contemplated in 21 C.F.R. § 101.45. Restaurants also may communicate nutrition claims through various “Nutritional Facts” formats set out in 21 C.F.R.

§ 101.9. But these options are not exclusive. Section 101.10 allows restaurants to provide information through “other reasonable means” as well.

**D. The NLEA Preemption Provision Applies to Regulation 81.50**

Congress has preempted state laws that are not “identical to” the requirements of section 343(r) and FDA regulations promulgated thereunder. The preemption statute provides, in part:

no State or political subdivision of a State may directly or indirectly establish under any authority or continue in effect as to any food in interstate commerce —

\* \* \*

(5) any requirement respecting any claim of the type described in section 343(r)(1) of this title, made in the label or labeling of food that is *not identical to* the requirement of section 343(r) of this title, except a requirement respecting a claim made in the label or labeling of food [by restaurants concerning cholesterol, saturated fat and dietary fiber and nutrients determined by the FDA to increase the risk of disease,] which is exempt under section 343(r)(5)(B)

....

21 U.S.C. § 343-1(a)(5) (emphasis added).

There can be no doubt that Regulation 81.50 imposes requirements “respecting any claim of the type described in section 343(r)(1)” because publishing calorie content is a nutrition claim under that section. *See supra* pp. 14-19. And Regulation 81.50 imposes requirements not “identical” to those of the federal law and its accompanying regulations, 21 C.F.R. § 101.10. *See supra* pp. 20-22; *see also NYSRA I*, 509 F. Supp. 2d at 362 (agreeing that old Regulation 81.50 imposed obligations “not identical to” FDA regulations). In contrast to the significant flexibility afforded by § 101.10, the city purports to dictate not only the content of nutritional claims, but even their the font-size, location, and the methodology of determining the number of calories. In this regard, Regulation 81.50(c)(1) requires a “verifiable analysis” of the caloric content of the

food. This differs from the standard in 21 C.F.R. § 101.10 of “reasonable bases that provide assurance that the food or meal meets the nutrient requirements for the claim.” This difference highlights the danger of a multiplicity of local standards around the country, each of which may impose non-uniform standards and procedures.

District courts have consistently applied the term “not identical to” as used in two subsections of Section 343-1(a) to preempt state laws. *See NYSRA I*, 509 F. Supp. 2d at 354 (“Because the City has chosen a regulatory approach that imposes different obligations than federal regulation of voluntary nutritional claims made by restaurants, the Court is compelled to find that Regulation 81.50 as drafted is preempted by federal law.”); *Reyes*, 2006 WL 3253579, at \*4 (construing section 343-1(a)(5)); *Vermont Pure Holdings, Ltd. v. Nestle Waters North America*, No. Civ. A. 03-11465 DPW, 2006 WL 839486, at \*5 (D. Mass. Mar. 28, 2006) (construing section 343-1(a)(1)); *Goya de Puerto Rico Inc. v. Santiago*, 59 F. Supp. 2d 274, 279 (D.P.R. 1999) (applying 343-1(a)(2)). Each of these courts held that the phrase “not identical to” means that state laws cannot be enforced to the extent they are “not identical to” applicable federal law and regulations. *C.f. Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 444-47 (2005) (applying similar preemption provision in 7 U.S.C. § 136v(b)); *see* 21 C.F.R. § 100.1(c) (“‘Not identical to’ does not refer to the specific words in the requirement but instead means that the State requirement directly or indirectly imposes obligations or contains provisions concerning the composition or labeling of food, or concerning a food container, that: (i) Are not imposed by or contained in the applicable provision (including any implementing regulation) of [the statute]; or (ii) Differ from those specifically imposed by or contained in the applicable provision (including any implementing regulation) of [the statute].”).

**E. The Dicta in *NYSRA I* Distinguishing Between “Voluntary” and “Involuntary” Statements Is Incorrect and Cannot Save Regulation 81.50**

In *NYSRA I*, the court’s opinion announced an idea that would give the defendants a “road map” for crafting a new regulation. This road map was not briefed or argued by any of the parties or *amici*. In holding the old Regulation 81.50 to be preempted, the court in *NYSRA I* wrote, in *dicta*, that the city could adopt a *different* regulation, which, the court said, would not be preempted. The opinion stated that the word “claim” under subsection (r) had to be limited to “voluntary” statements about the nutrient levels of food and not to include “involuntary” statements about the nutrient levels of food. Therefore, the opinion stated, a broader regulation, mandating calorie information from all restaurant chains of a certain size, would not be preempted because it would not regulate “voluntary” statements and therefore would not cover “nutrient content claims” within the meaning of § 343(r) and applicable regulations. According to the opinion, the mandatory/voluntary distinction was a “critical distinction.” 509 F. Supp. 2d at 362-63.<sup>12</sup> The city has now adopted the involuntary/voluntary distinction in promulgating its newly revised Regulation 81.50.

The distinction between so-called “voluntary” claims and state-mandated “involuntary” statements cannot be found in the statute or the regulations. *NYSRA I* appears, instead, to depend on the notion that the scope of the statute (and the agency’s concomitant power to regulate) varies depending on the “context” of whether the particular statement is “voluntary” or “compelled” by the state:

That an identical statement [e.g., 100 calories] may be both a claim and not a claim is not as inconsistent as may first appear. In the

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<sup>12</sup> The opinion repeats this distinction frequently. *See, e.g.*, 509 F. Supp. 2d at 357 (“this subsection [r] and its requirements only apply where a purveyor voluntarily chooses to make a covered claim”); *id.* (“if a restaurant voluntarily chooses to make a nutrient content claim . . . such a claim must be in compliance with FDA regulations”).



context of a voluntary statement made to its customers, the food purveyor is making an affirmative assertion as to the nutrient content of its product. In the context of a mandatory disclosure, the purveyor is making no claim at all; it is passively disclosing information as required by government regulations.

509 F. Supp. 2d at 361 n.14.

Even if it were permissible to subject the statute to a reading that requires determining the “context” of a particular statement on a case by case basis—and the statute contains no hint that this was Congress’ intent—the factual premise of this argument is incorrect. In following the mandates of the new city regulation, the restaurants would not be “passively disclosing information as required by government regulations.” This is not a situation in which the city would be sending the restaurants a list of what each restaurant would have to post. Each restaurant would have to determine for itself the caloric content of its food and then post it. By posting the number, the restaurants are certainly making a claim about the number of calories in the food. To any customer, this posting is the restaurant’s “affirmative assertion” of the nutrition content of its food. In any event, the place to look for the meaning of “claims” is in the statute and regulations—not in “context” in which the statements are made.

The “voluntary”/“mandatory” distinction announced in the district court’s opinion stems also from a misreading of § 343(r)(1). Section 343(r)(1) provides that nutrition information *required by subsection (q)* to be included in the nutrition fact panel on packaged foods is not a claim covered by subsection (r); but if that same information appears elsewhere in the labeling, it is a claim. The opinion in *NYSRA I* says this provision means that *any* mandatory nutrient disclosure, “whether required by section 343(q) or, with respect to restaurants, by state regulation,” is not a claim. 509 F. Supp. 2d at 362-63. However, section 343(r)(1) refers only to the specific type of mandatory disclosure required under subsection (q): “A statement of the

type required by paragraph (q) of this section that appears as part of the nutrition information required or permitted by such paragraph [q] is not a claim which is subject to [paragraph r] . . . .” Paragraph (q) does not refer to mandatory disclosures required by state regulation. The assertion that under section 343(r)(1) *all* mandatory disclosures are not claims is simply wrong: section 343(r)(1) states *only* that disclosures required by subsection (q) are not claims.

Moreover, the words “mandatory” and “voluntary” do not appear in the statute. Rather, the statute declares food to be “misbranded” if it bears a “claim . . . made in the label or labeling of the food which expressly or by implication . . . characterizes the level of any nutrient,” unless “the characterization of the level made in the claim uses terms which are defined in regulations of the Secretary.” 21 U.S.C. §§ 343(r)(1)(A), (r)(2)(A)(i). Another relevant portion of the statute directs that the agency “shall issue proposed regulations to implement [§ 343(r)] . . . [and that such regulations] shall permit statements describing the amount and percentage of nutrients in food which are not misleading and are consistent with the terms defined in [§ 343(r)(1)(A)(i)].”<sup>13</sup> These provisions make no voluntary/mandatory distinction. They apply to “claims” and “statements” of any kind.

The FDA’s regulations that define “claims” do not make a “voluntary”/“mandatory” distinction either. Rather, the regulations specifically define an “express nutrient content claim” to include *any* statement about the amount of a nutrient:

- (1) An expressed nutrient content claim is any direct statement about the level (or range) of a nutrient in the food, e.g., “low sodium” or “contains 100 calories.”
- (2) An implied nutrient content claim is any claim that:

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<sup>13</sup> NLEA § 3(b)(1)(A)(iv), 106 Stat. 4501 (set out in Historical and Statutory Notes after 21 U.S.C.A. § 343(r)).



- (i) Describes the food or an ingredient therein in a manner that suggests that a nutrient is absent or present in a certain amount (e.g., “high in oat bran”); or
- (ii) Suggests that the food, because of its nutrient content, may be useful in maintaining healthy dietary practices and is made in association with an explicit claim or statement about a nutrient (e.g., “healthy, contains 3 grams (g) of fat”).

21 C.F.R. § 101.13(b). Like the statute, the regulatory definition applies to “any direct statement” and “any claim.” It contains no exception for statements mandated by state law.

To be sure, there is a provision of the statute (and the corresponding regulations) that differentiates between voluntary and mandatory statements. But that difference does not bear on whether or not the statement is a “claim.” In fact, the regulations make that distinction *irrelevant* in determining what is and what is not a “claim.” Thus, subsection (q) (which applies to packaged foods) and the regulations promulgated under it, 21 C.F.R. § 101.9, require some information (e.g., calories) and permit other information (e.g., potassium). If a purveyor of packaged food makes a statement in the nutrition fact panel about the amount of (for example) potassium, it is doing so voluntarily. If the purveyor makes a statement in the fact panel about (for example) fat content, it is mandated by law. Yet both of these statements (the “voluntary” one and the “involuntary” one) are not “claims” when they are made in the nutrition fact panel; and both are “claims” when made “elsewhere in the label or in the labeling”—*i.e.*, not as part of the nutrition fact panel. 21 U.S.C. § 343(r)(1); 21 C.F.R. § 101.13(c).

Finally, the voluntary/mandatory distinction leads to absurd results. It is important to remember that the statutory and regulatory treatment of “claims” applies not just to restaurants, but to all purveyors of food, including those selling packaged foods. A purveyor of food might put on its package “low in fat.” The city and its *amici* claimed that this is the “core” of the

statute, and the court in *NYSRA I* found that such claims are the “heartland” of the statute. 509 F. Supp. 2d at 358. Any statement that a food is “low in fat” must satisfy specific regulations promulgated by the FDA. However, according to the “voluntary”/“mandatory” distinction in *NYSRA I*, if the city mandates that a food purveyor identify food “low in fat” (under whatever definition the city chooses to apply), then the statement is no longer a “claim” (because it is mandated by the city), and the city is free to override the federal regime, notwithstanding the preemption provision forbidding all state and local regulation that is not identical to the federal regime. Indeed, under this reasoning, each state and local government would be free to create its own (mandatory) “disclosure” regime about foods that are low in fat, high in calories, and so forth. And this flawed logic would apply, under this reasoning, not just to food sold in restaurants, but to all packaged food as well—the locality could compel any (mandatory) “disclosure” anywhere on the label other than in the federally required nutrition panel. New York City might, under this theory, require disclosure of the amount of calories of a serving of breakfast cereal on the front panel of the box. Such a mandatory disclosure would not be preempted by federal law governing the nutrition panel because it does not relate to the nutrition panel; and (under the voluntary/mandatory theory) it would not be preempted by federal law governing claims, because it is not a claim. That would eviscerate the federal regime.

**F. No “Tension” Within § 343-1(a) Requires Judicial “Reconciliation”**

The *NYSRA I* court stated that there is a “tension” between § 343-1(a)(4) [the preemption provision for subsection (q)] and § 343-1(a)(5) [the preemption provision for subsection (r)], and that this “tension” requires judicial “reconcil[iation].” 509 F. Supp. 2d at 362. According to this argument, the “tension” arises because subsection (q) exempts restaurants, and so the related preemption provision does not protect restaurants from state law. Since restaurants are

unprotected from state regulation by § 343-1(a)(4), the argument goes, the separate preemption provision that *does* apply to restaurants—subsection (a)(5)—must be construed narrowly, so as not to interfere with subsection (a)(4)’s exemption. According to the court’s opinion, applying 343-1(a)(5) as written—without engrafting onto it a distinction between “voluntary” and “involuntary” claims—“would read out of existence the state authority preserved by § 343-1(a)(4) and would result in the preemption under [subsection (a)(5)] of virtually all state regulations requiring restaurants to provide nutrition information.” 509 F. Supp. 2d at 362.

This is a false tension. Each subsection applies of its own force in different situations. Just because restaurants are not protected by one provision does not mean they are not protected by another. The relevant question is whether the subsection that does apply here—(a)(5)—preempts the regulation. The absence of preemption under another provision that does not apply in the circumstances of this case is simply irrelevant.

Moreover, the factual premise of the *dicta* is incorrect. Reading subsection (a)(5) as written would not “read out of existence” the state authority supposedly “preserved” by subsection (a)(4). In fact, by its terms, subsection (a)(5) expressly preserves state power to regulate “claims” made by restaurants concerning cholesterol, saturated fats, dietary fiber, and nutrients that the FDA has determined cause disease. *See* 21 U.S.C. §§ 343-1(a)(5), 343(r)(5)(B). In addition, with respect to all other claims (such as calories), states can enforce federal food labeling standards. *See* 21 C.F.R. § 101.2. Under the ruling in *Reyes v. McDonald’s Corp.*, even state tort laws may be enforced to the extent that they impose requirement that are “identical to” the federal requirements for food labeling. 2006 WL 3253579. Respectfully, it is the district court opinion’s suggested reading of subsection (a)(4) that would “read out of existence” the balance Congress struck in subsection (a)(5) *permitting*

state regulation of specified claims and *forbidding* non-identical state regulation of *other* claims (such as calories).

Finally, to the extent that any “tension” concerning preemption can be read into the statute, Congress explicitly delegated the responsibility of resolving the tension to the agency responsible for implementing the statute, and not to the courts. If the FDA finds that preemption under the statute has gone too far in any particular case, the FDA has the power (delegated by the Secretary of Health and Human Services) to exempt the state or local requirement from the operation of the preemption statute. The statute provides:

(b) Upon petition of a State or a political subdivision of a State, the Secretary may exempt from subsection (a), under such conditions as may be prescribed by regulation, any State or local requirement that—

- (1) would not cause any food to be in violation of any applicable requirement under Federal law,
- (2) would not unduly burden interstate commerce, and
- (3) is designed to address a particular need for information which need is not met by the requirements of the sections referred to in subsection (a) . . . .

21 U.S.C. § 343-1(b).

The FDA has promulgated a procedure for determining when it will exercise this authority and what a locality must do to invoke this procedure. 21 C.F.R. § 100.1. For whatever its reasons, in this case the city has not applied for an exemption under this procedure.

### **III. NYSRA IS LIKELY TO SUCCEED ON THE MERITS OF ITS FIRST AMENDMENT CLAIM**

#### **A. Regulation 81.50 Impermissibly Compels Speech**

The First Amendment guarantees “both the right to speak freely and the right to refrain from speaking at all.” *Wooley v. Maynard*, 430 U. S. 705, 714 (1977). The guarantee applies to compelled speech as it does to restraints on speech. *See id.* at 714-15. The right to refrain from

speaking “serves the same ultimate end as freedom of speech in its affirmative aspect.” *Pacific Gas & Elec. Co. v. Public Utilities Comm’n of California*, 475 U.S. 1, 11 (1986) (citation and internal quotations omitted). Compelled speech, like bans on speech, violates “the fundamental rule of protection under the First Amendment,” namely “that a speaker has the autonomy to choose the content of his own message.” *Hurley v. Irish-American Gay, Lesbian & Bisexual Group of Boston*, 515 U.S. 557, 573 (1995).

Thus, the Supreme Court has repeatedly struck down laws that compel a speaker to utter a message dictated by the government. The Court first invalidated a compulsion of speech in *West Virginia Board of Education v. Barnette*, 319 U. S. 624 (1943). The state required every child in public schools to recite the Pledge of Allegiance while saluting the American flag. The Court held that the First Amendment does not “le[ave] it open to public authorities to compel [a person] to utter” speech with which he does not agree. *Id.* at 634. In *Wooley v. Maynard*, 430 U.S. 705 (1977), the Court struck down a statute requiring automobile license plates to bear the State’s motto, “Live Free or Die.” The Court explained that requiring citizens to “use their private property as a ‘mobile billboard’ for the State’s ideological message” violated the First Amendment by compelling speech. *Id.* at 715. And in *Pacific Gas & Electric Co.*, the Court invalidated a state order requiring a utility company to include in its billing envelopes messages prepared four times a year by a consumer organization. The Court reasoned that, because corporations, like individuals, have “the choice of what not to say,” the order violated the First Amendment by forcing the company “to associate with speech with which [it] may disagree.” 475 U.S. at 15 (citation omitted).

The right not to speak “applies not only to expressions of value, opinion, or endorsement, but equally to statements of fact the speaker would rather avoid.” *Hurley*, 515 U.S. at 573-74

(citations omitted). In *Riley v. National Federation of the Blind of N.C., Inc.*, 487 U.S. 781 (1988), the Court found that a state law requiring fundraisers to disclose the percentage of funds that were actually paid to charity before seeking contributions from prospective donors violated the First Amendment. The Court refused to distinguish *Riley* from other compelled speech cases such as *Pacific Gas, Barnette*, or *Wooley*, “simply because [these latter cases] involved compelled statements of opinion while here we deal with compelled statements of ‘fact’: either form of compulsion burdens protected speech.” 487 U.S. at 797-98.

This protection against compelled speech also extends to commercial speech. See *United States v. United Foods, Inc.*, 533 U.S. 405, 410 (2001); *Zauderer v. Office of Disciplinary Counsel of the Supreme Court of Ohio*, 471 U.S. 626, 651 (1985) (“[U]njustified or unduly burdensome disclosure requirements might offend the First Amendment by chilling protected commercial speech.”); *International Dairy Foods*, 92 F.3d at 71 (“The right not to speak inheres in political and commercial speech alike . . .”) (citations omitted).

Regulation 81.50 impermissibly compels speech. In requiring the posting of the calorie counts of food items on menus and menu boards next to the price, the Regulation forces restaurants to use their most important tool for communicating with their customers to voice the government’s point of view, namely that patrons *must* consider the caloric content of food when ordering in a restaurant, and that calories are the only nutritional criterion that patrons need to consider. Some restaurants have never before published calorie information. Others have decided to provide comprehensive nutritional information to the public. By forcing all restaurants to post calories on their menus and menu boards, the city is requiring them to speak in a way that communicates the city’s message (“We have to tell people how to lead better lives”) regarding the significance of calories. Cf. *Int’l Dairy Foods*, 92 F.3d at 71-72 (striking



down law requiring labeling disclosure of rBST growth hormone in milk on the ground that “it compel[led] [plaintiffs] ‘to convey a message regarding the significance of rBST use that is “expressly contrary” to their views.’”) (citation omitted).

Plaintiff’s members do not want to convey the government’s message on their menus and menu boards. Many have determined that they disagree with the city’s viewpoint. To take one example, Ms. Haugen of Burger King Corporation explains:

BKC strongly disagrees with New York City’s regulation which requires it to isolate and post calorie information on menu boards in its restaurants. As most nutritionists know, overemphasis on any one nutrient such as calories can interfere with consumers obtaining a healthy, varied diet. Rather, BKC believes that nutrition information must be provided within the broader context of what it means to have a healthy diet, with an emphasis on consumers acquiring an energy balance while moderating intake of nutrients such as sodium, fats, trans fats and cholesterol....

While calories are important, BKC disagrees with the message that the New York regulation requires us to communicate to our customers. Limiting the information on menu boards to a single nutrient as a guideline to the healthfulness of a particular food can be misleading and can cause consumers to make the wrong food choice for themselves....

Emphasizing the calorie count of foods alone and in isolation on the menu boards will undermine our carefully developed program to communicate nutrition information to our customers....

Customers will attribute to BKC the message that calories are the most important nutrient and that a single calorie number is all they need to know. While this may be the City’s desired message, it is not the message that BKC wants to convey or with which it agrees....

We do not agree with the message [Regulation 81.50] will force us to send to our customers. We believe it will undermine the nutritional message that we have carefully developed and chosen to send to our customers.

Haugen Decl. ¶¶ 14-18; *accord* DeMuth Decl. ¶¶ 11, 17; LeClair Decl. ¶ 5; Liewen Decl. ¶¶ 4, 8-12; Roach Decl. ¶ 3. The city has suggested that these restaurants are free to provide disclaimers

and more comprehensive information on the menu or menu board. But the suggestion is completely unrealistic. Integrating calorie information *alone* in the manner required by the city results in cramped, cluttered, and confused menus and menu boards; providing information in a similar manner about all the other nutrients would be all but impossible.

Moreover, the vice of Regulation 81.50 exists regardless of whether a restaurant has—or has articulated—a specific disagreement with the city’s message. In *Barnette*, where the court held that a student did not have salute the American flag while reciting the Pledge of Allegiance, the unconstitutionality did not turn on whether the student was an atheist, or a pacifist, or of a particular religious denomination, or simply did not want to participate. 319 U.S. at 634-35. The same was true in *Pacific Gas & Electric*, where the actual content of the particular speech was not before the Court. Rather, the question was whether the government could require Pacific Gas to serve as a conduit for someone else’s speech every three months. For the Court, it was enough that the utility did not want to convey that speech at all.

In *United Foods*, the Supreme Court held that a monetary assessment imposed on mushroom growers pursuant to a federal act to fund advertisements of mushrooms violated the First Amendment because it compelled certain growers to subsidize commercial speech with which they disagreed. *United Foods*, 533 U.S. at 411-16. The government used the assessments to pay for generic advertising to promote the sale of mushrooms. *Id.* at 408. The plaintiff objected because it did not want to support a generic advertising campaign that promoted all mushrooms; it wanted to convey a message that its mushrooms were superior to mushrooms grown by other producers. *Id.* at 411. Notably, the Court drew a distinction between the (unconstitutional) statute before it, which “simply” required the mushroom growers to “support speech by others” by paying money, and even more onerous statutes (like the regulation here),



which force a party to “utter the speech itself.” *Id.* at 413; *see also* *Johanns v. Livestock Marketing Ass’n*, 544 U.S. 550, 568 (2005) (Thomas, J. concurring) (“The government may not, consistent with the First Amendment, associate individuals or organizations involuntarily with speech by attributing an unwanted message to them. . . .”).

The regulation here is far more offensive than the one at issue in *United Foods*, for it requires a restaurant to use its own forum to convey the Department of Health’s message as if it were the restaurant’s message. Similarly, Regulation 81.50 compares unfavorably to the state law struck down in *Wooley*. There, the plaintiff disagreed with the content conveyed on a state-issued license plate. Here, the city demands that the content be conveyed not on a government-issued license plate, but on the restaurant’s own signage.

The city may be free, as the mayor wishes, to use its own resources to “tell people how to lead better lives.” But the city is not free to put its message in the mouths of private citizens.

**B. Regulation 81.50 Impermissibly Burdens Protected Speech,  
Even When Evaluated Under Intermediate Scrutiny**

In *United Foods*, discussed *supra*, the Court found that because compelled speech is such a serious government intrusion, it did not need to apply the four-part test set out in *Central Hudson*, 447 U.S. 557 (1980). As noted above, this is an *a fortiori* case from *United Foods* because it involves compelled speech itself, rather than the subsidy at issue there.

Nevertheless, even under the more forgiving test of *Central Hudson*, Regulation 81.50 should be held unconstitutional.<sup>14</sup> In *Central Hudson*, the Supreme Court articulated a four-part

<sup>14</sup> In *United Foods*, the Court suggested that it might be time to rethink *Central Hudson*. The Court noted that many of its members had criticized *Central Hudson* in other cases as not adequately protecting First Amendment freedoms; but whether to overturn *Central Hudson* was a question left to a later case. The Court later granted *certiorari* to consider that very question, but procedural issues persuaded a majority of the Court not to reach the merits of that case. *See Nike, Inc. v. Kasky*, 539 U.S. 654, 665 (2003) (Stevens, J., concurring in dismissal of *certiorari*);

analysis for determining whether a government restriction on commercial speech violates the First Amendment. Under this test, a court must determine: (1) whether the regulated expression concerns lawful activity and is not misleading; (2) whether the asserted governmental interest is substantial; (3) whether the Regulation directly advances the asserted interest and (4) whether it is not more extensive than is necessary to serve that interest. 447 U.S. at 566.

The parties do not dispute the first two factors. The city does not contend that menus or menu boards without calorie information are misleading or concern unlawful activity: menus are speech plainly within the protection of the First Amendment. For its part, plaintiff agrees that the state has a substantial interest in public health. The Department of Health promulgated the Regulation to “reduce obesity and the many related health problems which obesity causes.” Notice of Adoption p. 2. This is the interest that the regulation must be shown to further.

The last two factors are at issue in this case. We do not believe that the city can show that the regulation directly advances public health to a material degree. Further, we do not believe that the city can show that its regulation is narrowly tailored to achieve its stated goal.

**1. Regulation 81.50 Does Not Advance The City’s Asserted Interest In Curbing Obesity in a “Direct and Material Way”**

To survive scrutiny under *Central Hudson*, the city must prove that Regulation 81.50 advances the government’s asserted, substantial interest in a “direct and material way.” *Edenfield v. Fane*, 507 U.S. 761, 767 (1993). The burden of justifying a restriction on commercial speech rests with the proponent of the restriction. *Id.* at 770. “[M]ere speculation or conjecture” will not suffice to sustain this burden. *Id.* Rather, the Department “must

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*id.* at 676 (2003) (Breyer, J., dissenting from dismissal of the writ of certiorari, suggested that heightened protection of commercial speech might be adopted).

demonstrate that the harms it recites are real and that its restriction will in fact alleviate them to a material degree.” *Id.* at 771. Otherwise, “a State could with ease restrict commercial speech in the service of other objectives that could not themselves justify a burden on commercial expression.” *Rubin v. Coors Brewing Co.*, 514 U.S. 476, 487 (1995) (quoting *Edenfield*, 507 U.S. at 771); *accord Greater New Orleans Broad. Ass’n v. United States*, 527 U.S. 173, 188 (1999).

The city’s Notice of Adoption never confronts the many unanswered questions concerning the effectiveness of its proposal. The *Keystone Forum Final Report* suggests a “clear need for more research” and highlights the many “research questions” that need answering, including “What type of information should be provided?.... How and where should information be provided, given the goals for providing such information? At point of sale, before sale, after sale for future purchases, etc.? Via menu board, brochure, table tent, poster, kiosk, etc.? If the information is accessed, how is it used? Under what circumstances is current behavior influenced and under what circumstances is future behavior influenced? For example, if consumers consume an extra 100 calories at lunch, will they eat a lighter dinner?.... Is information on the caloric content of food items more likely to be used by the consumer when presented alone or when embedded in general nutrition content information?” *Keystone Forum Final Report*, at 83-84.

All these questions are unanswered, not only by the city, but by the state-of-the-art research available. As the *Keystone Forum Final Report* put it,

Better and more timely information is needed regarding: the choices consumers are making regarding foodservice venues and foods, the values and motivations driving those choices, the factors that motivate changes in behaviors and attitudes, the potential value of nutrition information and other specific interventions, and

the best ways to promote changes in products or menus that are relevant to weight management.

\* \* \*

Evidence regarding how and why consumers use nutrition information is limited. Outstanding questions include how consumers process and use such information, what measurable contribution the information can make to the goal of managing weight gain and obesity, where the point of decision-making is for away-from-home-foods consumers, and what effect information may have on consumer choice, eating behavior, and store revenue. Likewise lacking are data with regard to whether one format or another alters the rate of consumer usage of the information.

*Id.* at 46, 69; *see id.* at 22 (“The research base on obesity is incomplete and imperfect regarding some aspects of the problem, such as the potential effectiveness of specific interventions aimed at assisting consumers with managing their energy intake.”); *id.* at 65, 67 (listing as a “Basic Research Need” information on “What information, if any, regarding the nutritional composition of menu items prompts consumers to take action and choose items to manage weight?”).

Dr. David B. Allison of the University of Alabama studied the evidence cited by the Department of Health. Dr. Allison concluded:

[T]here is no body of data showing that implementation of R81.50 would affect actual behavior or weight either in the short-term or in the long-term nor is there any body of evidence that the specific manner in which the R81.50 would require provision of caloric information would lead to better results in the short-term or long-term than any other method. **Thus, I conclude that there is not competent and reliable evidence that providing restaurant patrons with calorie information on menu items will reduce individual or population levels of obesity. Nor is there evidence that the method of providing caloric information mandated by R81.50 will reduce levels of obesity more than the methods currently used by the affected restaurants to provide this information.**

Allison Decl. pp. 29-30 (emphasis in original). Dr. Allison went on to state that the only things that could be drawn from the incomplete state of knowledge were speculation and “conjecture.”

*Id.* at 30.

As for the survey that the Department of Health conducted, Dr. Allison notes a number of profound limitations and flaws. The study was designed to compare purchases at chain restaurants before Regulation 81.50 became effective with purchases at the same restaurants after implementation. As Dr. Allison explains, “The City’s own study . . . has many very substantial limitations, falls markedly below accepted standards for research in the scientific community, is interpreted in a scientifically unjustifiable manner, and does not offer competent and reliable evidence regarding any effects [of Regulation 81.50].” Allison Decl. p. 22. In addition, the Board’s use of the study in its Notice of Adoption is misleading at best. The Board claims that menu board labeling is essential and other forms of communication are “woefully inadequate.” It cites the experience of patrons at Subway for this proposition. Yet the “observation logs” created during the study show that the calorie information was *not on the menu boards of most Subway restaurants during the period studied*. In fact, other forms of communication (apparently the “woefully inadequate” ones) *were* noticed by patrons even when the information was not on the menu board. Allison Decl. pp. 25-26.

Finally, the limited reach of the regulation calls its effectiveness into question. The city admittedly has chosen *not* to regulate at least two thirds (and possibly 90%) of the restaurant meals served in New York City. If evidence actually showed that putting calories on menu boards would save lives, the Board of Health would not limit its reach to 10% of the city’s restaurants. Imagine a city health regulation forbidding unsanitary practices, but only at chain restaurants. Such a regulation would be unthinkable in the face of evidence that improved sanitation practices would save lives at all restaurants. The lack of uniformity here suggests that even the city understands that the scientific evidence does not support Regulation 81.50. And without such evidence, the regulation fails. *Edenfield*, 507 U.S. at 770-71.

**2. Regulation 81.50's Infringement On Speech Is More Extensive Than Necessary To Serve The City's Asserted Interest**

Even when a governmental burden on speech is effective to a material degree, it must still employ a means "narrowly tailored to achieve the desired objective." *Lorillard Tobacco v. Reilly*, 533 U.S. 525, 556 (2001) (internal quotations omitted); *see also Bad Frog Brewery, Inc. v. N.Y. State Liquor Auth.*, 134 F.3d 87, 100-01 (2d Cir. 1998) ("*Central Hudson's* fourth criterion . . . requires consideration of whether the prohibition is more extensive than necessary to serve the asserted state interest.") (citations omitted). A restriction on speech is "more extensive than necessary" if "less intrusive" alternatives are available. *Rubin*, 514 U.S. at 491; *Bad Frog Brewery*, 134 F.3d at 101.

In this case, there are many alternatives for providing customers with caloric information in restaurants that would not so heavily burden restaurants' First Amendment rights by co-opting their most important communication tool and using it to convey a message with which they disagree. These alternatives include signs directing consumers to comprehensive nutritional information, posters with complete nutritional information, food wrappers with such information, counter-mats with such information, stanchions and flip-charts with such information, and prominently displayed brochures. Many restaurants proposed such alternatives, but the city spurned them. *See* Horn Decl. ¶¶ 2-4; Munoz Decl. ¶ 12 & Exs. A, B; Smoot Decl. ¶¶ 8-10 & Exs. C, D; *Keystone Forum Final Report* App. J at pp. 128-33 (listing alternatives including websites, server-delivered information, second menus, health-oriented menu sections, health-related symbols for menus, tray liner information, packaging information, reference books, posters, handouts, brochures). Signs directing consumers to nutritional information elsewhere in a restaurant could be placed prominently on or near menu boards. Moreover, the city clearly anticipates customers making repeated visits to those restaurants subject to the regulation; so any



caloric information reviewed even after the time of purchase would inform the patron during later visits. Regulation 81.50, however, requires listing of calories on menus and menu boards in the specific manner compelled by the regulation: “adjacent or in close proximity such as to be clearly associated with the menu item, using a font and format that is at least as prominent, in size and appearance, as that used to post either the name or price of the menu item.” Reg. 81.50(c).

**C. *Zauderer* And *Sorrell* Are Inapplicable**

In defending the old Regulation 81.50, the city argued that the regulation was merely a “disclosure requirement” subject to “reasonableness” review under the Supreme Court’s decision in *Zauderer v. Office of Disciplinary Counsel*, 471 U.S. 626 (1985), and the Second Circuit’s decision in *National Electrical Manufacturers Ass’n v. Sorrell*, 272 F.3d 104 (2d Cir. 2001). The city relied most heavily on *Zauderer*. There, the state required that contingency-fee lawyers disclose to contingency-fee clients that they might have to pay litigation costs if their claims proved unsuccessful. 471 U.S. at 650. The Court explained that “an advertiser’s rights are adequately protected as long as disclosure requirements are reasonably related to the *State’s* interest in preventing deception of consumers.” 471 U.S. at 651 (footnote omitted, emphasis added).

In *Sorrell*, the Second Circuit applied *Zauderer* and upheld a statute that barred the dumping of products containing mercury and, to effect that ban, required sellers to “inform the purchaser or consumer that mercury [was] present in the item and that the item [could] not be disposed of or placed in a waste stream destined for disposal until the mercury is removed and reused, recycled, or otherwise managed to ensure that it [did] not become part of solid waste or wastewater.” 272 F.3d at 107 n.1.



*Zauderer* and *Sorrell* are inapplicable here, for at least three independent reasons. *First*, Regulation 81.50 is not an adjunct to a broader regulatory regime that makes certain conduct unlawful, as in *Sorrell*. *Second*, Regulation 81.50 bears on controversial speech and for that reason cannot be analogized to the “purely factual” and “non-controversial” disclosure at issue in *Sorrell*. *Third*, the Regulation cannot be justified as reasonably related to the prevention of consumer deception—the touchstone of *Zauderer* as limited by *United Foods*.

**1. Regulation 81.50 Does Not Prevent Unlawful Conduct**

Regulation 81.50, unlike the law at issue in *Sorrell*, is not an adjunct necessary to implement a law that makes certain activity unlawful. In *Sorrell*, Vermont had made unlawful the dumping of mercury-containing products together with ordinary waste. It would have been virtually meaningless to pass such a law without also providing consumers with information about which products were subject to this prohibition—information that was not otherwise known to them. Regulation 81.50 serves no analogous law-enforcement purpose. The distinction between laws mandating speech to further a comprehensive regulatory regime and those that do not was discussed at length in *United Foods*, 533 U.S. at 412-13.

**2. Regulation 81.50 Does Not Limit Itself to Factual, Non-Controversial Information**

Regulation 81.50 goes beyond the documentation of uncontroversial information. Because *Zauderer* and its progeny focus on the prevention of deception, their reach is limited to “purely factual and uncontroversial information[.]” *Zauderer*, 471 U.S. at 651. *Sorrell*, by its own terms, applies only to laws requiring disclosure of accurate, factual non-controversial information. As the Circuit acknowledged, a regulation “[r]equiring actors in the marketplace to espouse particular opinions would likely raise issues not [there] presented[.]” 272 F.3d at 114 n.5.

Plaintiff's members vigorously dispute the city's point of view that informed nutritional decisions can be made by considering calories out of the context of other nutritional values. *See supra* pp. 31-32. The Keystone Forum observed that "[t]he range of views on this topic, outlined here, may help the reader to understand the complexity of the issue and the diverse and sometimes strong views that the topic generates among stakeholders." *Keystone Forum Final Report* at 70.

The Second Circuit's decision in *International Dairy Foods Association* is instructive. There, the Court enjoined the enforcement of a Vermont law that required dairy producers to label all products made with rBST, a growth hormone used to treat dairy cattle. 92 F.3d at 69, 74. While the disclosure mandated by the statute was undoubtedly true as a factual matter, the law required milk producers "'to convey a message regarding the significance of rBST use that [was] 'expressly contrary' to their views.'" *Id.* at 71 (citation omitted). The Second Circuit applied *Central Hudson* and struck down the law. *Id.* at 74.<sup>15</sup>

### 3. Regulation 81.50 Does Not Prevent Misleading Speech

Regulation 81.50 does not purport to protect against potentially misleading speech. In defending the original Regulation 81.50, the city argued that *Zauderer* applied to any "disclosure" requirement. We disagree. The correct reading of *Zauderer* is that it permitted mandatory disclosure requirements only when they further the "State's interest in preventing deception of consumers." 471 U.S. at 651 (footnote omitted). This limitation is the necessary consequence of earlier Supreme Court decisions defining the boundary between misleading speech, which is not protected at all by the First Amendment, and commercial speech, which is

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<sup>15</sup> *United Foods* had not yet been decided when the Second Circuit decided *International Dairy*, so the court applied *Central Hudson*.

protected.

The Supreme Court has long held that certain forms of “speech” are simply beyond the ambit of First Amendment protection. *See Paris Adult Theatre I v. Slaton*, 413 U.S. 49 (1973) (obscenity); *Chaplinsky v. New Hampshire*, 315 U.S. 568 (1942) (fighting words). Misleading commercial speech falls within this category. *See In re R.M.J.*, 455 U.S. 191, 203 (1982) (“Misleading advertising may be prohibited entirely.”); *Virginia State Bd. of Pharmacy v. Virginia Citizens Consumer Council, Inc.*, 425 U.S. 748, 771 (1976) (same). As one scholarly text explains, “certain commercial speech is not entitled to protection; the informational function of advertising is the First Amendment concern and if an advertisement does not accurately inform the public about lawful activity, it can be suppressed.” Johnny H. Killian, George A. Costello and Kenneth R. Thomas, *The Constitution of the United States of America: Analysis & Interpretation*, at 1180 (Sen. Doc. 108-17) (2002) (footnote omitted).

Thus, in developing First Amendment protection for commercial speech, the Supreme Court has expressly linked the validity of so-called “disclosure” requirements to their ability to protect against potentially misleading speech. As the Court explained in *Virginia State Board*, the state may regulate potentially “deceptive or misleading” commercial speech by “requir[ing] that a commercial message appear in such a form, or include such additional information, warnings, and disclaimers, as are necessary to prevent its being deceptive.” 425 U.S. at 771 n.24. Similarly, the Court explained in *R.M.J.*, the state “may not place an absolute prohibition on certain types of *potentially* misleading information . . . if the information also may be presented in a way that is not deceptive . . . . Although the potential for deception and confusion is particularly strong in the context of advertising professional services, restrictions upon such advertising may be no broader than reasonably necessary to prevent the deception.” 455 U.S. at

203 (emphasis added); *see also Rubin*, 514 U.S. at 494 (Stevens, J., concurring) (“[A]ny description of commercial speech that is intended to identify the category of speech entitled to less First Amendment protection should relate to the reasons for permitting broader regulation: namely, commercial speech’s potential to mislead.”).

The *Zauderer* case fits comfortably within this line of cases. It holds that a “disclosure requirement” affecting commercial transactions must protect against potentially misleading information. It has been expressly so limited by the Supreme Court in *United Foods*, which rejected application of *Zauderer* to the law there at issue on the ground that there was “no suggestion” in *United Foods* “that the mandatory assessments imposed to require one group of private persons to pay for speech by others are somehow necessary to make voluntary advertisements nonmisleading for consumers.” 533 U.S. at 416. We recognize that *Sorrell* rejected this limitation of *Zauderer*, but this aspect of *Sorrell* cannot be reconciled with *United Foods*, which was decided the same year as *Sorell*. *Zauderer*’s identification of the “State’s interest in preventing deception of consumers,” (471 U.S. at 651 (footnote omitted)), was not merely the fortuitous byproduct of the particular facts that happened to be before the Court. It was, rather, the necessary consequence of earlier decisions defining the boundary between misleading speech, which is not protected at all by the First Amendment, and commercial speech, which *is* protected.

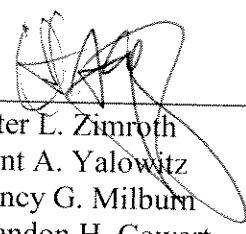
**CONCLUSION**

For the reasons stated above, the Court should grant plaintiff's motion for declaratory relief on its preemption claim and for preliminary injunctive relief on its Preemption and First Amendment claims.

Dated: January 31, 2008  
New York, New York

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